

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ALMA LASERS LTD. and  
ALMA LASERS, INC.,

Plaintiffs,

v.

PALOMAR MEDICAL  
TECHNOLOGIES, INC. and  
THE GENERAL HOSPITAL CORPORATION,

Defendants.

PALOMAR MEDICAL  
TECHNOLOGIES, INC. and  
THE GENERAL HOSPITAL CORPORATION,

Counterclaimants,

v.

ALMA LASERS LTD. and  
ALMA LASERS, INC.,

Counterdefendants.

C.A. No. 08-574-JJF

**FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT**

Plaintiffs Alma Lasers Ltd., and Alma Lasers, Inc. (together "Alma" where appropriate), for their Complaint against Defendants Palomar Medical Technologies, Inc. ("Palomar") and The General Hospital Corporation, d/b/a Massachusetts General Hospital ("MGH"), state as follows:

**The Parties**

1. Plaintiff Alma Lasers Ltd. is a corporation organized and existing under the laws of the country of Israel and having its principal place of business at 14 Halamish, Caesarea Industrial Park, Caesarea, Israel 38900.

2. Plaintiff Alma Lasers, Inc. is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business at 485 Half Day Road, Suite 100, Buffalo Grove, Illinois.

3. Upon information and belief, Defendant Palomar is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 82 Cambridge Street, Burlington, Massachusetts.

4. Upon information and belief, Defendant MGH is a not-for-profit corporation organized and existing under the laws of the State of Massachusetts, doing business as the Massachusetts General Hospital, and having its principal place of business at 55 Fruit Street, Boston, Massachusetts 02114.

#### **The Nature of the Action**

5. This is an action for Declaratory Judgment of non-infringement and/or invalidity as to a patent owned by and/or licensed to Palomar and/or MGH, under 35 U.S.C. §§ 101, 102, 103, 112, and 271. The patent is U.S. Patent No. 6,997,923 ("the '923 patent"). A copy of the '923 patent is attached as Exhibit A.

#### **Jurisdiction and Venue**

6. This Court has jurisdiction pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Venue properly lies in this Court under 28 U.S.C. §§ 1391(b), 1391(c), and 1400 because Palomar resides in this District.

#### **Palomar's Threats**

8. In 2007, Alma Lasers, Inc., Palomar, and MGH executed a settlement agreement resolving various patent and trade dress issues then in dispute. The dispute involved Palomar's

claims of infringement regarding Alma's hair removal products. The settlement agreement did not encompass the '923 patent at issue here, which involves an apparatus and method for skin treatment.

9. Alma Lasers, Inc. currently markets its skin treatment products throughout the United States, and Alma Lasers, Inc., or its predecessors, have been selling its products in the United States since 2003. Many of Palomar's products compete with Alma's products.

10. Beginning in March 2008, Palomar sought to license its '923 patent to Alma in connection with Alma's skin treatment products. In a series of discussions and communications between March 2008 and July 31, 2008, Palomar took the position that various Alma skin treatment products infringe the '923 patent and demanded that Alma enter into a license agreement to cover past alleged infringement and future use of Alma's products. In the negotiations, Palomar made specific demands regarding licensing terms, including the royalty rate to be paid to Palomar. Alma refused enter into a license agreement because none of its products infringe the '923 patent and because the '923 patent is invalid.

11. On July 31, 2008, Patricia Davis, General Counsel for Palomar, wrote to Alma reiterating Palomar's contention that Alma's products infringe the '923 patent. In that letter, Ms. Davis specifically accused Alma of infringing claim 20 of the '923 patent.

12. Alma desires to sell its products, free from the specter of Palomar's allegations of infringement of the '923 patent.

13. Palomar's licensing demand and detailed accusations of infringement, including infringement of claim 20 of the '923 patent, are a real and imminent threat of a restraint on the free exploitation of Alma's products. This threat inhibits Alma from selling its products free from the specter of an infringement suit against itself and its customers.

14. On November 20, 2009 Palomar and MGH filed a First Amended Counterclaim in this court alleging infringement of the '923 patent through Alma's sales of various Alma skin treatment products.

### **COUNT I**

#### **Declaratory Judgment of Non-Infringement and Invalidity of United States Patent No. 6,997,923**

15. Alma repeats and realleges the allegations contained in preceding paragraphs 1-14, inclusive, as if fully set forth herein.

16. The '923 patent, entitled "Method and Apparatus for EMR Treatment," was issued on February 14, 2006. A copy of the '923 patent is attached as Exhibit A. On information and belief, Palomar and MGH are the owners of the '923 patent.

17. On information and belief, Palomar is a licensee under the '923 patent.

18. Alma's past and present activities in making, using, selling, importing, and/or offering for sale in the United States its skin treatment products, including but not limited to the Alma Pixel CO<sub>2</sub> Omnifit Handpiece, the Alma Pixel CO<sub>2</sub> Skin Resurfacing System, and the Harmony products do not infringe any valid claim of the '923 patent, either literally or under the doctrine of equivalents. Alma does not infringe and has not infringed, either directly, or by active inducement, or contributorily, any valid and enforceable claim of the '923 patent.

19. The '923 patent is invalid under one or more of the provisions of Title 35 of the United States Code, including the provisions of 35 U.S.C. §§ 101, 102, 103, and 112 and/or the judicially created doctrine of obviousness-type double patenting. This includes, for example and without limitation, invalidity of one or more claims under § 102 as being anticipated by International Publication No. WO 99/17668 ("the Anderson '668 publication" or "the '668 publication"); invalidity of one or more claims under § 103 as being obvious in light of

combinations of prior art references, such as International Publication No. WO 99/17,668 in combination with secondary references; and invalidity of one or more claims under § 112 on grounds of indefiniteness, lack of written description (i.e., that the inventors did not have possession of the full scope of the presently claimed invention as construed by defendants), and lack of enablement (i.e., that the inventors did not provide an enabling disclosure of the presently claimed invention as construed by defendants).

20. As a consequence of the foregoing, there is an actual and justiciable controversy between Alma, Palomar and MGH over the infringement and validity of the '923 patent, with respect to which Alma is entitled to a declaratory judgment in its favor.

## **COUNT II**

### **Unenforceability Due To Inequitable Conduct**

21. The '923 patent is unenforceable because of the commission of inequitable conduct in its procurement. Inventor R. Rox Anderson ("Anderson") knew of withheld material information in International Publication No. WO 99/17,668 and in U.S. Patent No. 6,436,127, and he withheld this information in the prosecution of the '923 patent with a specific intent to deceive the PTO.

#### **A. Persons Having a Duty of Candor**

22. The '923 patent in suit was filed in the United States Patent and Trademark Office ("PTO") on December 27, 2001, as application Serial No. 10/033,302 ("the '302 application"). The '302 application claimed priority to a provisional application filed as application Serial No. 60/258,855, on December 28, 2000. The inventors, their attorneys and persons substantively involved in the prosecution of the '923 patent had a duty of candor and good faith in their dealings with the PTO.

**B. The Materiality of the Anderson '668 Publication and '127 Patent to the Claims of the '923 Patent**

23. The specification of the '923 patent states that it relates to methods and apparatus for using various forms of electromagnetic radiation, including both coherent and non-coherent optical radiation, for a variety of medical and dermatology treatments ('923 patent, col. 1, lines 10-23). The treatments relevant to the subject matter of the '923 patent include, among other conditions, the skin disorder known as psoriasis ('923 patent, col. 1, line 27). The "Detailed Description" in the '923 patent specification specifically mentions treatment of psoriasis in several locations (see, e.g., col. 7, line 6; col. 15, line 26).

24. U.S. Patent No. 6,436,127 ("the '127 patent"), was filed on October 8, 1998 as application Serial No. 09/169,083 ("the '083 application") and issued on August 20, 2002. The '127 patent is entitled "Phototherapy Methods and Systems," and it names Anderson as the lead inventor. The '083 application claims priority to provisional application Serial No. 60/061,487, filed October 8, 1997. The contents of the '083 application, which eventually issued as the '127 patent, were published on April 15, 1999 as International Application No. WO 99/17668 ("the Anderson '668 publication" or "the '668 publication"). Based on its publication date of April 15, 1999, the '668 publication constitutes prior art to the '923 patent under 35 U.S.C. § 102(b). Based on its filing date in the United States of October 8, 1998, the '127 patent constitutes prior art to the '923 patent under 35 U.S.C. § 102(e) as of its issuance on August 20, 2002.

25. The Anderson '668 publication, and '127 patent, include at least the following description that is material to the claims of the '923 patent. The invention of the '668 publication relates to methods and systems for treating psoriasis and other skin disorders ('668 publication, p. 1, lines 4-6, hereinafter "page:lines"). The method involves exposing the patient's skin to radiation and delivering radiation to selected treatment areas using a laser (*Id.*, 4:31-5:8). The

treatment method involves scanning an infected area to create a digital map of affected and unaffected areas (*Id.*, 12:20-25). Thereafter, the positioning system delivers treatment radiation only to the affected areas of the skin (*Id.*, 13:10-16). The automated system can deliver radiation to areas only having psoriasis, and avoid non-treatment of portions of the area that do not have actual psoriasis, but have a portwine stain or a wart (*Id.*, 17:22-26).

26. The device described in the Anderson '668 publication uses a scanner/controller to direct the treatment beam to different positions on the patient's skin (*Id.*, 20:15-19). The system can use different collimated UV sources, including Nd:YAG lasers (*Id.*, 23:20-30). The system can be used manually to distinguish between areas that are being treated and areas that are not being treated (*Id.*, 27:27-30). An example of the device that provides automated treatment is a fiber optic pen system shown in Fig. 6A (*Id.*, 32:23-25). Optical fibers deliver the radiation signal by a fiber optic bundle and a beamsplitter (*Id.*, 33:11-14). Individual fibers within the fiber optic bundle may deliver only diagnostic radiation, deliver only therapeutic radiation, receive only diagnostic radiation, or some combination thereof (*Id.*, 35:23-26). Rather than using all of the fibers in the fiber optic bundle, a single fiber can deliver and/or receive diagnostic radiation and/or therapeutic radiation (*Id.*, 35:26-33). Alternatively, a fiber optic comb, such as the one described in U.S. Patent No. 5,300,097 ("the '097 patent") can be modified to perform selective delivery of therapeutic radiation (*Id.*, 36:7-11). Each prong of the comb is equivalent to the fiber optic pen and can deliver diagnostic radiation and/or therapeutic radiation (*Id.*, 36:22-26). Some prongs of the comb can be dedicated to delivering therapeutic radiation and other prongs can be dedicated to delivering diagnostic radiation (*Id.*, 36:16-23).

27. The '127 patent and/or the Anderson '668 publication is material to at least claims 20-29 of the '923 patent. An exemplary detailed comparison between claim 20 of the '923

patent, as necessarily construed by Defendants in alleging infringement of the Alma products, and the disclosure of the '668 publication, is set forth as follows:

<b><u>U.S. Patent No. 6,997,923</u></b>	<b><u>Anderson '668 publication</u></b>
20. A method for performing a therapeutic treatment on a patient's skin by utilizing	Treatment of psoriasis on skin by radiation ('668 publication, 4:31-5:8). The '923 patent includes psoriasis as an intended dermatology treatment of the '923 device ('923 patent, 1:26, 7:6).
a multi-focal optical system to concentrate applied treatment radiation of selected wavelength at a plurality of selected, three-dimensionally located, treatment portions,	A therapeutic dose of radiation is applied to the skin. Figs. 6A and 6B show a fiber optic pen with a beamsplitter to apply radiation through one or more selected fibers based on digital map or manual selection to selected treatment portions ('668 publication, 20:15-19, 27:27-30, 32:23-25, 35:26-33).
such that following application of the treatment radiation the treatment portions are separated from one another by non-treatment portions.	Dosage delivered to treat only affected areas of skin, and leaves non-treated areas ('668 publication, 13:10-16, 17:22-26).

The identified portions of the '668 publication are material to similar recitations in claims 21-29 of the '923 patent.

28. The materiality of the '668 publication to the claims of the '923 patent is also demonstrated by how the PTO Examiner would have used the '668 publication in assessing the patentability of the claims of the '923 patent. In the prosecution of the application for the '923 patent, in a Response to Office Action ("First Response") filed on or about February 23, 2004, at p. 11, Anderson distinguished the Fuller U.S. Patent No. 5,968,033 ("Fuller") by stating that Fuller does not include a multi-focal optical system for directing radiation to a plurality of treatment portions in a selected volume that are located within untreated portions of that volume. The disclosure of the '668 publication, as described above, refutes or is inconsistent with this



argument of patentability and would have provided the PTO Examiner with a reference having the features of the claims allegedly missing from the Fuller patent.

29. In the prosecution of the application for the '923 patent, in the First Response, at pp. 12-13, Anderson distinguished the Baranov U.S. Patent No. 6,059,820 ("Baranov") by stating that Baranov does not generate a multiplicity of treatment portions, separated from one another by untreated portions, over an extended region. At page 15 of the First Response, Anderson distinguished Baranov by stating that Baranov allegedly does not teach a multi-focal optical system. At page 16 of the First Response, Anderson distinguished Baranov by stating that Baranov does not teach irradiating a plurality of spatially separated treatment portions in a temporal sequence; i.e., the irradiated spots are allegedly generated simultaneously and not sequentially over time. The disclosure of the '668 publication, as described above, refutes or is inconsistent with this argument of patentability and would have provided the PTO Examiner with a reference having the features of the claims allegedly missing from the Baranov patent.

30. In the prosecution of the application for the '923 patent, in a Response filed on or about January 6, 2005 ("Second Response"), at pp. 12-13, Anderson distinguished the Tankovich U.S. Patent No. 6,050,990 ("Tankovich") by stating that Tankovich does not generate a multiplicity of treatment portions, separated from one another by untreated portions. At page 12 of the Second Response, Anderson distinguished Tankovich by stating that Tankovich allegedly does not teach multiple foci. At page 13 of the Second Response, Anderson distinguished Tankovich by stating that Tankovich does not teach or suggest a controller that would selectively activate the radiation source for successive irradiation. The disclosure of the '668 publication, as described above, refutes or is inconsistent with this argument of patentability and would have

provided the PTO Examiner with a reference having the features of the claim allegedly missing from the Tankovich patent.

31. In the prosecution of the application for the '923 patent, in the Second Response, at p. 15, Anderson distinguished the Eppstein U.S. Patent No. 5,885,211 ("Eppstein") by stating that Eppstein does not concentrate radiation onto treatment portions within a volume that are separated from one another by untreated portions. At page 16 of the Second Response, Anderson distinguished Eppstein by stating that Eppstein does not teach or suggest a controller for selectively activating a the radiation source for successive irradiation. The disclosure of the '668 publication, as described above, refutes or is inconsistent with this argument of patentability and would have provided the PTO Examiner with a reference having the features of the claims allegedly missing from the Eppstein patent.

**C. Anderson's Knowledge and Understanding of the Scope Being Accorded to the Claims of the '923 Patent by Palomar**

32. On or about April 4, 2002, Anderson signed a declaration, which was filed in the PTO in the '302 application for the '923 patent. In that declaration, Anderson declared, among other things, that he had reviewed and understood the contents of the patent application filed on December 27, 2001 as Application No. 10/033,302, including the claims. On information and belief based upon a review of records in public databases at the U.S. PTO and in databases of foreign patent offices, Anderson, in conjunction with Palomar and/or MGH, has continued to prosecute patent applications in the U.S. PTO, and in foreign countries, that relate to, or claim the benefit of, the '302 application that issued as the '923 patent. On information and belief based upon a review of records in public databases at the U.S. PTO, Anderson, in conjunction with Palomar and/or MGH, has continued to prosecute at least the following patent applications in the U.S. PTO relating to the '923 patent: (1) Serial No. 11/235,697, filed September 21, 2005;

(2) Serial No. 11/599,786, filed November 15, 2006; and, (3) Serial No. 11/760,333, filed June 8, 2007.

33. Anderson's knowledge and understanding of the scope of the claims being accorded to the '923 patent by Palomar is further confirmed by his statements in a Palomar press release dated November 11, 2008, entitled "Palomar Medical Technologies and Reliant Technologies Announce Launch of a Fractional Technology Licensing Program." In that press release, Palomar, Reliant Technology and MGH indicate that they are "owners of the fundamental intellectual property" in the "fractional space." In that press release, Anderson is quoted as follows:

We are excited to be a part of this program. Fractional treatment is a broad technology that enhances safety and efficacy over that of traditional light-based aesthetic treatments. Our work has already helped many people around the world. This program enables participants to benefit from years of research and continue development of an important new approach.

The press release indicates that the licensing program includes the '923 patent as well as "the '923 patent family -- jointly owned with and licensed by Palomar from MGH," which includes application Serial No. 11/235,697.

**D. Anderson's Knowledge and Understanding of the Materiality of the '668 Publication and '127 Patent**

34. On or about November 13, 1998, Anderson signed a declaration, which was filed in the PTO in the '083 application for the '127 patent. In that declaration, Anderson declared, among other things, that he had reviewed and understood the contents of the patent application filed on October 8, 1998, as Application No. 09/169,083. The disclosure of the '083 application was eventually published as the '668 publication. On information and belief based upon a review of records in public databases at the U.S. PTO and in databases of foreign patent offices,

Anderson, in conjunction with MGH, has continued to prosecute patent applications in the U.S. PTO, and in foreign countries, that relate to, or claim the benefit of, the '083 application that issued as the '127 patent. On information and belief based upon a review of records in public databases at the U.S. PTO, Anderson, in conjunction with MGH, has continued to prosecute at least the following patent applications in the U.S. PTO relating to the '127 patent: (1) Serial No. 10/224,059, filed August 20, 2002 and issued as U.S. Patent No. 6,984,228; (2) Serial No. 11/293,905, filed December 5, 2005; and, (3) Serial No. 11/758,067, filed June 8, 2007. The actions of Anderson described in this paragraph demonstrate that Anderson fully understood the contents of the '668 publication and that he was repeatedly confronted with the contents of that application, and its subject matter, throughout the period during which the '302 application for the '923 patent was pending in the U.S. PTO.

35. On information and belief based upon a review of public databases of records in the U.S. PTO and foreign patent offices (database known as "INPADOC"), Anderson and MGH both consider the psoriasis treatments being developed by Anderson to be valuable technology. On information and belief based on a review of public database records of foreign patent offices, at least the Australian counterpart of the '668 publication was licensed to Photomedex, Inc ("Photomedex"). According to information on the Photomedex website (<http://www.photomedex.com/about/Anderson.php>), Photomedex is a company that develops proprietary fiber-optic systems for treatment of dermatological applications such as psoriasis. On information and belief based on review of documents at the Photomedex website, Anderson serves on the Scientific Advisory Board of Photomedex and serves as a consultant to Photomedex.

**E. Anderson's Intentional Failure to Cite the '668 Publication or the '127 Patent as Prior Art in the Prosecution of the '923 Patent**

36. Neither the '668 publication nor the '127 patent were cited as prior art in the prosecution of the '923 patent. Anderson filed multiple information disclosure statements ("IDS") in the prosecution of the '923 patent, which cited more than 100 U.S. patents, 50 foreign references, 46 technical publications, and 11 pending patent applications. On or about April 25, 2002, Anderson filed an IDS in the prosecution of the '923 patent that cited the Fuller and Baranov patents, neither of which named Anderson as an inventor and both of which were cited by the Examiner in rejecting the claims.

37. On or about June 6, 2002, Anderson filed an IDS in the prosecution of the '923 patent that cited approximately ninety-nine (99) U.S. patents, forty-four (44) foreign references, forty-six (46) technical publications, and six pending patent applications. The cited U.S. patents included two Anderson patents that related to hair removal and one Anderson patent that related to treatment of wrinkles. The cited technical publications included a 2001 article by Anderson and Altshuler, entitled "Extended Theory of Selective Photothermolysis," published in *Lasers in Surgery and Medicine*, 29:416-432 (2001), which could not be used as prior art to the '923 patent by the Examiner without further information because of its publication date. Although the IDS included this technical publication of Anderson that did not qualify as prior art to the '923 patent, the IDS did not include the more relevant Anderson '668 publication which would be prior art based on its publication date. The cited pending applications included three applications that list Anderson as a co-inventor. Although the IDS included pending applications of Anderson, the IDS did not include the more relevant pending '083 application, which issued as the '127 patent.

38. On or about January 7, 2003, Anderson filed an IDS in the prosecution of the '923 patent that cited five pending applications, one U.S. patent, and four foreign references. On or

about August 11, 2003, Anderson filed an IDS in the prosecution of the '923 patent that cited one U.S. patent and two foreign references. On or about March 9, 2004, Anderson filed an IDS in the prosecution of the '923 patent that cited one U.S. patent. On or about May 21, 2004, Anderson filed an IDS in the prosecution of the '923 patent that cited one U.S. patent. On January 10, 2005, Anderson filed an IDS in the prosecution of the '923 patent that cited two U.S. patents.

39. During the pendency of the '302 application for the '923 patent, which lasted from the filing of the non-provisional '302 application on December 27, 2001 until the issuance of the '923 patent on February 14, 2006, Anderson filed seven separate information disclosure statements in the prosecution of the '923 patent, which cited more than one hundred (100) U.S. patents, fifty (50) foreign references, forty-six (46) technical publications, and eleven (11) pending patent applications. Among the 100 U.S. patents, 50 foreign references, 46 technical publications, and 11 pending applications cited in the prosecution of the '923 patent were several of Anderson's own patents and patent applications, as well as prior art that Anderson successfully distinguished from the pending claims of the application for the '923 patent. During that same time period, Anderson prosecuted the '083 application, which issued as the '127 patent on August 20, 2002; filed two continuation applications of the '083 application on August 20, 2002 (Serial No. 10/224,059) and December 5, 2005 (Serial No. 11/293,905) and filed applications in several foreign countries based upon the application that was published at the '668 publication. In light of the numerous citations of information less relevant than the '668 publication and the '127 patent in the prosecution of the '923 patent; the numerous citations of Anderson's own patents, pending applications and technical papers in the prosecution of the '923 patent; the citations of references in the '923 patent that, on their face, do not qualify as prior art to the '923 patent; the

contemporaneous on-going prosecution and issuance of the '127 patent and the on-going prosecution of applications pertaining to the '668 publication; Anderson's own statements in declarations that he understood both the contents of the claims of the application for the '923 patent and the disclosure of his own '668 publication; and, the high degree of relevance of the '668 publication and '127 patent to the distinctions being made by Anderson over the prior art in the '923 patent; the single most reasonable inference able to be drawn from this evidence is that Anderson knew of the withheld material information in the '668 publication and '127 patent, and that he withheld this information in the prosecution of the '923 patent with a specific intent to deceive the PTO.

40. Pursuant to the provisions of 35 U.S.C. § 285, this action qualifies as an exceptional case supporting an award of attorney fees, costs and expenses for Alma.

**Prayer for Relief**

WHEREFORE, Alma respectfully requests the following relief:

- a. the entry of judgment declaring that Alma has not infringed the '923 patent;
- b. the entry of judgment declaring that the '923 patent is invalid;
- c. the entry of judgment declaring that the '923 patent is unenforceable as a result of the commission of inequitable conduct in its procurement;
- d. the entry of judgment declaring this to be an exceptional case pursuant to 35 U.S.C. § 285 and awarding to Alma its reasonable attorneys' fees expended in bringing and maintaining this action; and
- e. award of such other and further relief as the Court deems just and proper.

ASHBY & GEDDES

*/s/ John G. Day*

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